



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED  
JUN 20 2003  
TECH CENTER 1600/2900

Applicants: Hiten D. Madhani and Eric S. Lander  
Application No.: 09/439,969 Group: 1636  
Filed: November 12, 1999 Examiner: Gerald G. Leffers, Jr.  
Confirmation No.: 2363  
For: TARGETS OF THE MAP KINASE PATHWAY IN THE  
DEVELOPMENTAL SWITCH IN YEAST

#17

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450	
on <u>June 16, 2003</u>	<u>Beverly Weinberger</u>
Date	Signature
<u>Beverly Weinberger</u>	
Typed or printed name of person signing certificate	

REQUEST FOR CORRECTED FILING RECEIPT  
FOR UTILITY APPLICATION

Office of Initial Patent Examination  
Customer Service Center  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

We hereby request that the following item of information be added to the Filing Receipt for the subject application received in this office on January 10, 2003.

The error and correction appears below.

Please add in the Applicant(s) section --ERIC S. LANDER, CAMBRIDGE, MA--

The correct inventorship in the application is Hiten D. Madhani, San Francisco, CA, and Eric S. Lander, Cambridge, MA. A request for correction/amendment of inventorship under 37 C.F.R. § 1.48(a) was previously filed at the U.S. Patent and Trademark Office on February 12,

2002, for the above-identified application. Copies of the previously filed documents are enclosed:

1. Request for Correction/Amendment of Inventorship Under 37 C.F.R. § 1.48(a);
2. Statement Under 37 C.F.R. § 1.48(a)(2) by Eric S. Lander;
3. Substitute Declarations for Patent Application executed by Hiten D. Madhani and Eric S. Lander;
4. Written Consent of Assignee in Correction of Inventorship Under 37 C.F.R. § 1.48(a)(5) and Certificate Under 37 C.F.R. § 3.73(b);
5. Assignment by Eric S. Lander and Recordation Form Cover Sheet; and
6. Postcard stamped by the PTO acknowledging receipt of the above-listed documents.

Entry of the requested change of inventorship was acknowledged in the Office Action mailed from the U.S. Patent and Trademark Office on January 14, 2003 (copy enclosed).

Enclosed is a copy of the Filing Receipt with changes noted in red.

Pursuant to instructions in the February 29, 2000 O.G., we hereby request that the errors which are identified above be corrected in the captioned application to which this request for correction is directed. It is understood that the Patent Office will issue an automatically-generated, corrected Filing Receipt in this and, if applicable, any other affected applications.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Lisa M. Treannie

Lisa M. Treannie

Registration No.: 41,368

Telephone: (978) 341-0036

Facsimile: (978) 341-0136

Concord, MA 01742-9133

Date: 6/14/03

**COPY**
 Commissioner for Patents  
 Washington, DC 20231  
 www.uspto.gov

APPLICATION NUMBER	FILING DATE	GRP ART UNIT	FIL FEE REC'D	ATTY. DOCKET NO	DRAWINGS	TOT CLAIMS	IND CLAIMS
09/439,969	11/12/1999	1636	1202	2825.1013002	11	18	7

CONFIRMATION NO. 2363

CORRECTED FILING RECEIPT



\*OC00000009335593\*

 21005  
 HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
 530 VIRGINIA ROAD  
 P.O. BOX 9133  
 CONCORD, MA 01742-9133

Date Mailed: 01/06/2003

Receipt is acknowledged of a CPA in this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

**Applicant(s)**

HITEN D. MADHANI, SAN FRANCISCO, CA;

**ERIC S. LANDER, CAMBRIDGE, MA****Domestic Priority data as claimed by applicant**
 This appln claims benefit of 60/108,399 11/13/1998  
 and claims benefit of 60/114,849 01/06/1999
**Foreign Applications**

If Required, Foreign Filing License Granted: 12/06/1999

CPA filed on: 12/23/2002

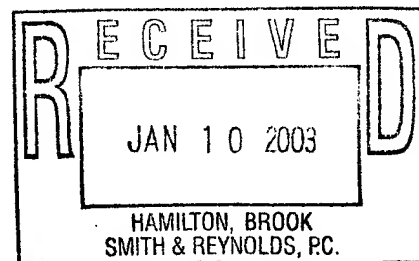
Projected Publication Date: 04/17/2003

Non-Publication Request: No

Early Publication Request: No

**Title**

TARGETS OF THE MAP KINASE PATHWAY IN THE DEVELOPMENTAL SWITCH IN YEAST

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Preliminary Class

435

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**LICENSE FOR FOREIGN FILING UNDER  
Title 35, United States Code, Section 184  
Title 37, Code of Federal Regulations, 5.11 & 5.15**

**GRANTED**

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

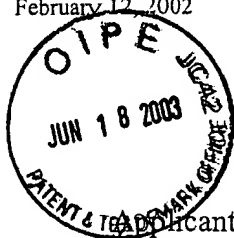
This license is to be retained by the licensee and may be used at any time on or after the effective date thereof unless it is revoked. This license is automatically transferred to any related applications(s) filed under 37 CFR 1.53(d). This license is not retroactive.

The grant of a license does not in any way lessen the responsibility of a licensee for the security of the subject matter as imposed by any Government contract or the provisions of existing laws relating to espionage and the national security or the export of technical data. Licensees should apprise themselves of current regulations especially with respect to certain countries, of other agencies, particularly the Office of Defense Trade Controls, Department of State (with respect to Arms, Munitions and Implements of War (22 CFR 121-128)); the Office of Export Administration, Department of Commerce (15 CFR 370.10 (j)); the Office of Foreign Assets Control, Department of Treasury (31 CFR Parts 500+) and the Department of Energy.

**NOT GRANTED**

No license under 35 U.S.C. 184 has been granted at this time, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" DOES NOT appear on this form. Applicant may still petition for a license under 37 CFR 5.12, if a license is desired before the expiration of 6 months from the filing date of the application. If 6 months has lapsed from the filing date of this application and the licensee has not received any indication of a secrecy order under 35 U.S.C. 181, the licensee may foreign file the application pursuant to 37 CFR 5.15(b).

FILE COPY



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

**COPY**

Applicant: Hiten D. Madhani  
Application No.: 09/439,969 Group: 1636  
Filed: November 12, 1999 Examiner: G. Leffers, Jr.  
For: Targets of the Map Kinase Pathway in the Developmental Switch in Yeast

CERTIFICATE OF MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>2/12/02</u>	<u>Stephanie L. Carta</u>
Date	Signature
Stephanie L. Carta	
Typed or printed name of person signing certificate	

**RECEIVED**  
JUN 20 2003  
TECH CENTER 1600/2900

REQUEST FOR CORRECTION/AMENDMENT OF INVENTORSHIP

UNDER 37 C.F.R. § 1.48(a)

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Applicant requests that the inventorship be corrected and the above-captioned application, including page 1 of the specification, be amended to add Eric S. Lander as inventor. With such amendment, Hiten D. Madhani and Eric S. Lander are the joint inventors of the subject application.

Enclosed herewith are the following documents: Statement under 37 CFR §1.48(a)(2) by Eric S. Lander; an executed Declaration by the actual inventors as required by §1.63; Written Consent of the Assignee to the inventorship change with Certificate under §3.73(b); and a check in the amount of \$130.00 in payment of the processing fee as set forth in §1.17(i).

09/439,969

-2-

Please charge any deficiency or credit any overpayment in the fees that may be due in this matter to Deposit Account No. 08-0380. A copy of this letter is enclosed for accounting purposes.

Respectfully submitted,  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Lisa M. Treannie  
Lisa M. Treannie  
Registration No.: 41,368  
Telephone: (978) 341-0036  
Facsimile: (978) 341-0136

Concord, MA 01742-9133

Date:

2/12/02

::ODMA\MHODMA\iManage;260933;1  
LMT/BPT/slc  
10/12/01

PATENT APPLICATION  
Docket No.: 2825.1013-002

**COPY**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

JUN 20 2003

TECH CENTER 1600/2900



Applicant: Hiten D. Madhani  
Application No.: 09/439,969 Group: 1636  
Filed: November 12, 1999 Examiner: G. Leffers, Jr.  
For: Targets of the Map Kinase Pathway in the Developmental Switch in Yeast

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on <u>2/12/02</u>	<u>Stephanie L. Carta</u>
Date	Signature
<u>Stephanie L. Carta</u>	
Typed or printed name of person signing certificate	

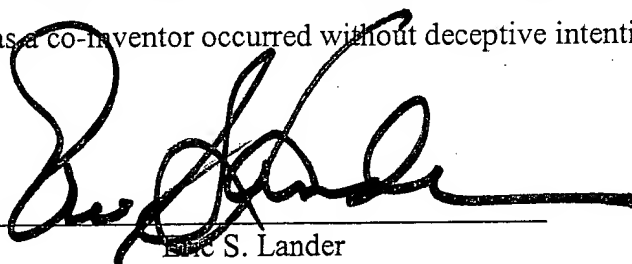
STATEMENT UNDER 37 C.F.R. § 1.48(a)(2) BY ERIC S. LANDER

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

I, Eric S. Lander, hereby state that I am a co-inventor with Hiten D. Madhani of the subject matter claimed in the above-captioned application as filed. The error of omitting my name as a co-inventor occurred without deceptive intention on my part.

Name

  
Eric S. Lander

Date 18 Dec 2002

# COPY

DOC. NO. 2825.1013-002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Substitute Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

TARGETS OF THE MAP KINASE PATHWAY IN THE DEVELOPMENTAL SWITCH IN YEAST

the specification of which (check one)

☐ is attached hereto.☒ was filed on November 12, 1999 as United States ApplicationNumber or PCT International Application No. 09/439,969

and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			Priority Not Claimed	Certified Copy Filed?	
				YES	NO
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

60/108,399  
(Application Number)November 13, 1998  
(Filing Date)60/114,849  
(Application Number)January 6, 1999  
(Filing Date)

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TECH CENTER 1600/2900



I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)
(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)
(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)
(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)

As a named inventor, I hereby appoint the attorneys and/or agents associated with  
**Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, MA 01742-9133,**  
**Customer No. 21005,**

and \_\_\_\_\_,

to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please send correspondence to:

☒ Customer No. 21005  
**HAMILTON, BROOK, SMITH & REYNOLDS, P.C.**  
530 Virginia Road  
P.O. Box 9133  
Concord, MA 01742-9133

or

☐ Address as follows:

Direct telephone calls to: Lisa M. Treannie, Esq. Telephone No.: 978-341-0036

Direct facsimiles to: Lisa M. Treannie, Esq. Facsimile No.: 978-341-0136

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full name of sole

or first inventor Hiten D. Madhani

Inventor's Signature Hiten D. Madhani Date 11-6-01

Residence 216 Downey Street

San Francisco, California 94117

Citizenship United States of America

Post Office Address same as above

Full name of second joint

inventor, if any Eric S. Lander

Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Residence 151 Bishop Allen Drive  
Cambridge, Massachusetts 02139

Citizenship United States of America

Mailing Address same as above

\_\_\_\_\_  
-----

# COPY

DOCUMENT NO. 2825.1013-002

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Substitute Declaration for Patent Application

As a named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated next to my name;

I believe I am the original, first and sole inventor (if only one name is listed) or an original, first and joint inventor (if plural names are listed in the signatory page(s) commencing at page 3 hereof) of the subject matter which is claimed and for which a patent is sought on the invention entitled

TARGETS OF THE MAP KINASE PATHWAY IN THE DEVELOPMENTAL SWITCH IN YEAST

the specification of which (check one)

- ☐ is attached hereto.
- ☒ was filed on November 12, 1999 as United States Application

Number or PCT International Application No. 09/439,969

and was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is known by me to be material to patentability as defined in 37 C.F.R. §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent or inventor's certificate, or of any PCT international application having a filing date before that of the application on which priority is claimed:

<u>Prior Foreign Application(s)</u>			<u>Priority</u> Not Claimed	<u>Certified</u> Copy Filed?	
				YES	NO
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	[ ]	[ ]	[ ]
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	[ ]	[ ]	[ ]
_____ (Number)	_____ (Country)	_____ (Day/Month/Year filed)	[ ]	[ ]	[ ]

I hereby claim the benefit under 35 U.S.C. §119(e) of any United States provisional application(s) listed below.

60/108,399  
(Application Number)

November 13, 1998  
(Filing Date)

60/114,849  
(Application Number)

January 6, 1999  
(Filing Date)



I hereby claim the benefit under 35 U.S.C. 120 of any United States application(s), or 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of 35 U.S.C. 112, I acknowledge the duty to disclose information known by me to be material to patentability as defined in 37 C.F.R. 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)
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(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)
(Application Serial No.)	(Filing date)	(Status: patented, pending, abandoned)

As a named inventor, I hereby appoint the attorneys and/or agents associated with  
**Hamilton, Brook, Smith & Reynolds, P.C., 530 Virginia Road, P.O. Box 9133, Concord, MA 01742-9133,**  
**Customer No. 21005,**

and \_\_\_\_\_,

to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.

Please send correspondence to:

[ X ] Customer No. 21005  
HAMILTON, BROOK, SMITH & REYNOLDS, P.C.  
530 Virginia Road  
P.O. Box 9133  
Concord, MA 01742-9133

or

[ ] Address as follows:

Direct telephone calls to: Lisa M. Treannie, Esq. Telephone No.: 978-341-0036  
Direct facsimiles to: Lisa M. Treannie, Esq. Facsimile No.: 978-341-0136

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

-----  
Full name of sole

or first inventor Hiten D. Madhani

Inventor's Signature \_\_\_\_\_ Date \_\_\_\_\_

Residence 216 Downey Street  
San Francisco, California 94117

Citizenship United States of America

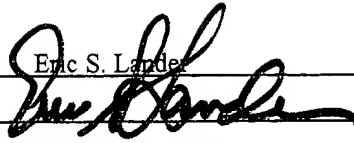
Post Office Address same as above  
-----

Full name of second joint

inventor, if any \_\_\_\_\_

Eric S. Lander

Inventor's Signature \_\_\_\_\_



Date \_\_\_\_\_

18 Dec 2001

Residence \_\_\_\_\_

151 Bishop Allen Drive

Cambridge, Massachusetts 02139

Citizenship \_\_\_\_\_

United States of America

Mailing Address \_\_\_\_\_

same as above

-----

**COPY**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



Applicant: Hiten D. Madhani  
Application No.: 09/439,969 Group: 1636  
Filed: November 12, 1999 Examiner: G. Leffers, Jr.  
For: Targets of the Map Kinase Pathway in the Developmental Switch in Yeast

<b>CERTIFICATE OF MAILING</b>	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231	
on <u>2/12/02</u>	<u>Stephanie L. Carta</u>
Date	Signature
Stephanie L. Carta	
Typed or printed name of person signing certificate	

WRITTEN CONSENT OF ASSIGNEE IN CORRECTION OF INVENTORSHIP  
UNDER 37 C.F.R. §1.48(a)(5)

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Whitehead Institute for Biomedical Research is the assignee of the entire right, title and interest in the referenced patent application and does hereby consent to the addition of Eric S. Lander as an inventor in the application.

A Certificate under 37 C.F.R. § 3.73(b) is being filed concurrently with this Written Consent.

Respectfully submitted,

By Patricia Granahan  
Patricia Granahan, Esq.  
Intellectual Property Manager  
Whitehead Institute for Biomedical Research

Cambridge, Massachusetts 02142  
Date: December 2, 2001

**COPY**



Docket No. 2825.1013-002

**CERTIFICATE UNDER 37 C.F.R. § 3.73(b)**

Applicant: Hiten D. Madhani

Application No.: 09/439,969

Filed: November 12, 1999

For: Targets of the Map Kinase Pathway in the Developmental Switch in Yeast

Whitehead Institute for Biomedical Research, a

non-profit research institution

(Name of Assignee)

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

certifies that it is

- A. ☒ the assignee of the entire right, title and interest in the patent application identified above.
- B. ☐ an assignee together with ☐ of the entire right, title and interest in the patent application identified above. A separate Certificate under 37 CFR § 3.73(b) is attached.

The right, title and interest of the above-named assignee in the patent application identified above is established by virtue of:

- A. ☒ An assignment from the inventor of the patent application identified above. The assignment was recorded in the Patent and Trademark Office at Reel 011017, Frames 0354-0356, or for which a copy thereof is attached.

OR

- B. ☐ A chain of title from the inventor(s) of the patent application identified above, to the current assignee as shown below:

1. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
2. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.
3. From: \_\_\_\_\_ To: \_\_\_\_\_  
The document was recorded in the Patent and Trademark Office at  
Reel \_\_\_\_\_, Frame \_\_\_\_\_, or for which a copy thereof is attached.

☐ Additional documents in the chain of title are attached.

☐ Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: December 2, 2001

Name: Patricia Granahan, Esq.

Title: Intellectual Property Manager

Signature: Patricia Granahan

**COPY**

**RECORDATION FORM COVER SHEET  
PATENTS ONLY**

**FILE COPY**

To the Honorable Commissioner of Patents and Trademarks: Please record the attached original documents or copy thereof.

1. Name of conveying party(ies)

Eric S. Lander



2. Name and address of receiving party(ies)

Name: Whitehead Institute for Biomedical Research

Internal Address: \_\_\_\_\_

Additional name(s) of conveying party(ies) attached? ☐ Yes ☒ No

3. Nature of conveyance:

☒ Assignment

☐ Merger

☐ Security Agreement

☐ Change of Name

☐ Other \_\_\_\_\_

Execution Date: December 18, 2001

Street Address: Nine Cambridge Center

City: Cambridge

State: MA

ZIP: 02142

Additional name(s) & address(es) attached? ☐ Yes ☒ No

4. Application number(s) or patent number(s):

If this document is being filed together with a new application, the execution date of the application is: \_\_\_\_\_

A. Patent Application No.(s)

09/439,969

B. Patent No.(s)

Additional numbers attached? ☐ Yes ☒ No

5. Name and address of party to whom correspondence concerning document should be mailed:

Name: Lisa M. Treannie, Esq.

Internal Address: \_\_\_\_\_

Hamilton, Brook, Smith & Reynolds, P.C.

Street Address: 530 Virginia Road, P.O. Box 9133

City: Concord State: MA ZIP: 01742-9133

6. Total number of applications and patents involved: [1]

7. Total Fee (37 C.F.R. 3.41)..... \$ 40.00

☒ Enclosed

☒ Authorized to charge any deficiencies or credit any overpayment to deposit account

☐ Authorized to be charged to deposit account

8. Deposit account number:

08-0380

(Attach duplicate copy of this page if paying by deposit account)

**DO NOT USE THIS SPACE**

9. Statement and signature.

*To the best of my knowledge and belief, the foregoing information is true and correct and any attached copy is a true copy of the original document.*

Lisa M. Treannie

Name of Person Signing

Lisa M. Treannie

Signature

2/12/02

Date

Total number of pages including cover sheet, attachments, and document: [3]



**COPY**

Docket No. 2825.1013-002  
Multi-Sole

ASSIGNMENT

WHEREAS, I, **Eric S. Lander**, together with co-inventor, **Hiten D. Madhani**, have invented a certain improvement in **Targets of the Map Kinase Pathway in the Development Switch in Yeast**, described in an application for Letters Patent of the United States, the specification of which:

☐ is being executed on even date herewith and is about to be filed in the United States Patent Office;

☒ was filed on November 12, 1999 as Application No. 09/439,969;

☐ was patented under U.S. Patent No. ☐ on ☐.

WHEREAS, **Whitehead Institute for Biomedical Research**, a corporation organized and existing under the laws of the **State of Delaware** and having a usual place of business at **Nine Cambridge Center, Cambridge, Massachusetts 02142** (hereinafter "ASSIGNEE") desires to acquire an interest therein in accordance with agreements duly entered into with me;

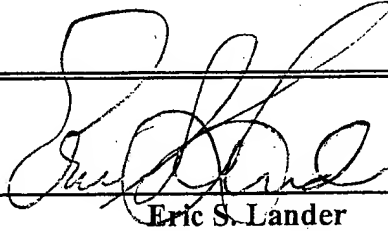
NOW, THEREFORE, to all whom it may concern be it known that for and in consideration of said agreements and of other good and valuable consideration, the receipt of which is hereby acknowledged, I have sold, assigned and transferred and by these presents do hereby sell, assign and transfer unto said ASSIGNEE, its successors, assigns and legal representatives, my entire right, title and interest in and throughout the United States of America, its territories and all foreign countries, in and to said invention as described in said application, together with my entire right, title and interest in and to said application and such Letters Patent as may issue thereon; said invention, application and Letters Patent to be held and enjoyed by said ASSIGNEE for its own use and behalf and for its successors, assigns and legal representatives, to the full end of the term for which said Letters Patent may be granted as fully and entirely as the same would have been held by me had this assignment and sale not been made; I hereby convey all rights arising under or pursuant to any and all international agreements, treaties or laws relating to the protection of industrial property by filing any such applications for Letters Patent. I hereby acknowledge that this assignment, being of my entire right, title and interest in and to said invention, carries with it the right in ASSIGNEE to apply for and obtain from competent authorities in all countries of the world any and all Letters Patent by attorneys and agents of ASSIGNEE's selection and the right to procure the grant of all such Letters Patent to ASSIGNEE for its own name as assignee of the entire right, title and interest therein;

AND, I hereby further agree for myself and my executors and administrators to execute upon request any other lawful documents and likewise to perform any other lawful acts which may be deemed necessary to secure fully the aforesaid invention to said ASSIGNEE, its successors, assigns and legal representatives, but at its or their expense and charges, including the execution of applications for patents in foreign countries, and the execution of substitution, reissue, divisional or continuation applications and preliminary or other statements and the giving of testimony in any interference or other proceeding in which said invention or any application or patent directed thereto may be involved;

AND, I do hereby authorize and request the Commissioner of Patents of the United States to issue such Letters Patent as shall be granted upon said application or applications based thereon to said ASSIGNEE, its successors, assigns, and legal representatives.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my seal the date set forth below.

Inventor's Signature: \_\_\_\_\_

  
Eric S. Lander


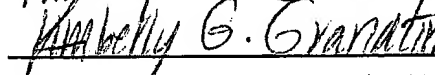
State/Commonwealth \_\_\_\_\_

of \_\_\_\_\_

County of \_\_\_\_\_

Then personally appeared before me the above-named **Eric S. Lander** and acknowledged that he executed the foregoing instrument as his free act and deed this 18<sup>th</sup> day of December, 2001.

(SEAL)

 Notary Public  
 (print name)  
My Commission expires 8/4/06

# COPY

Initials: LMT/BPT/slc Docket No.: 2825.1013-002 Date: February 12, 2002

This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedures 37 C.F.R. 1.8:

- ☒ Request for Correction/Amendment of Inventorship under 37 C.F.R. 1.48
- ☒ Statement under 37 C.F.R. 1.48
- ☒ Statement under 37 C.F.R. 1.63
- ☒ Written Consent of Assignee in Correction of Inventorship under 37 C.F.R. 1.48
- ☒ Certificate under 3.73(b)
- ☒ Check for \$130.00
- ☒ Declaration/Power of Attorney
- ☒ Authorization to Charge Fees
- Other \_\_\_\_\_

Applicant: Hiten D. Madhani  
Application No.: 09/439,969  
Title: Targets of the MAP Kinase Pathway in the Developmental Switch in Yeast

Date received by the PTO:



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/439,969	11/12/1999	HITEN D. MADHANI	2825.1013002	2363

21005 7590 01/14/2003

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EXAMINER

LEFFERS JR, GERALD G

ART UNIT

PAPER NUMBER

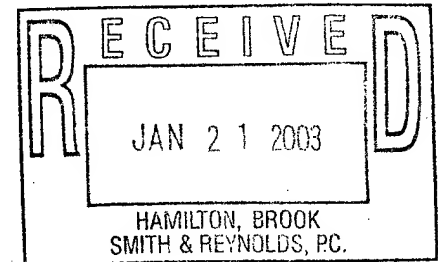
1636

DATE MAILED: 01/14/2003

16

**COPY**

Please find below and/or attached an Office communication concerning this application or proceeding.



# Office Action Summary

Application No.

09/439,969

Applicant(s)

MADHANI, HITEN D.

Examiner

Gerald G Leffers Jr.

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 23 December 2002.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 14-16, 18 and 19 is/are pending in the application.
- 4a) Of the above claim(s) 1-8, 14, 16 and 18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 15 and 19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Continued Prosecution Application***

The request filed on 12/23/02 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/439,969 is acceptable and a CPA has been established. An action on the CPA follows.

Claims 1-9, 11, 14-16 and 18-19 are pending in this application, with claims 1-8, 14, 16 and 18 withdrawn from consideration as being directed to a nonelected invention. Claims 9, 11, 15 and 19 are under consideration.

It is noted that applicants' have not filed a response to the previous office action, mailed 12/19/01 as Paper No. 11. Accordingly, this action is FINAL.

### ***Request for Correction/Amendment of Inventorship Under 37 C.F.R. 1.48(a)***

Receipt is acknowledged of a request to change the inventorship for the instant application, filed 3/8/02 as Paper No. 12. The change to include Eric S. Lander has been approved.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 11, 15 and 19 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly

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connected, to make and/or use the invention. **For claims 9, 11 and 15, this rejection is maintained for reasons of record in Paper No. 8 and 11. Claim 19 has been included in the instant rejection because of amendment of the claim in Paper No. 10 to include specific gene embodiments (e.g. the specific genes claimed by claims 9 and 15).**

***Response to Arguments Filed in Paper No. 10***

Applicant's arguments filed in Paper No. 10 have been fully considered but they are not persuasive. Applicants' response essentially argues: 1) the coding sequences for PGU1 and TOT10/YELO33W were publicly available at the time of filing at a web site sponsored by Stanford University, and 2) a contemporaneous paper by Blanco et al teaches the sequence of PGU1. These arguments are not persuasive on several grounds. A critical element of applicants' invention is the presence of regulatory sequences for each of the recited *genes* that are responsive to modulation of the MAPK filamentous pathway of yeast. Thus, it is not just the coding sequences of the recited genes that are critical to practicing the claimed methods. It is not at all clear that the information provided by the cited web site would have taught to one of skill in the art the necessary regulatory sequences required to practice the claimed invention (i.e. MAPK-responsive regulatory sequences). Such MAPK-responsive regulatory sequences would have to be determined by trial-and-error experimentation. Moreover, one of the requirements for biological materials under 37 §§ C.F.R. 1.801-1.809 is that the material be readily available to the public. There is no guarantee that the cited web sites will be available to the public for the entire term that would be granted upon issuance of a patent on the instant claims.

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With regard to claim 19, it is not at all clear that the relevant coding and regulatory sequences were available to the public at the time of filing for each of the additional genes recited in the claim. Absent any evidence to the contrary regarding the availability to the public of such gene sequences, a biological deposit is required for each of the cited sequences.

Claim 19 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This rejection is maintained for reasons of record in Paper No. 11, mailed 12/19/01 and repeated below.**

Claim 19, as amended, is now directed to a series of specific genes that are purported to be modulated as part of the filamentation MAPK pathway in a fungus. The claim recites a method in which the gene encoding a particular MAPK pathway protein is transformed into a suitable host cell such that the host cell expresses the desired gene encoding a constituent of the MAPK pathway. The level of expression of the desired gene is compared between control cells and cells treated with a test compound. A difference in the level of expression of the desired gene for the test and control cells indicates that the test agent modulates the expression of the purported MAPK-pathway gene. Thus, a critical feature of applicants' invention is the presence of regulatory sequences that are part of the gene encoding the MAPK-pathway protein that is responsive to the filamentation MAPK pathway. The claims also encompass a potentially large genus of genes in that the claims are directed towards "a filamentation



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MAPK pathway in a fungus". Thus, a large number of potential genes (including MAPK responsive elements) from a large number of different fungi are encompassed by the rejected claim.

The cited passages from the specification provided in Paper No. 10 for support of the claimed method (page 3, first paragraph under REMARKS), wherein each of the regulatory/coding sequences recited in the amended claims is expressed as part of a method to identify modulators of the recited gene, does not provide literal support for the claimed method. Thus, the amendment to include each of the recited genes is considered to be NEW MATTER.

Moreover, the specification does not provide any description of the genes recited in claim 19 other than a name. It is not at all clear that each of the gene sequences, including MAPK-responsive regulatory elements, were described in the prior art such that one of skill in the art could envision nucleic acid constructs which are responsive to the MAPK pathway. Given the lack of description of any sequences in the specification, particularly of MAPK-responsive elements, the lack of description of such MAPK-responsive sequences in the prior art for the recited genes and the scope of potential genes from different fungal sources encompassed by the rejected claim, one of skill in the art would not have been able to envision a representative number of embodiments of genes sufficient to describe the entire genus. Therefore, one of skill in the art would reasonably have concluded applicants were not in possession of the claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 9, 11, 15 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This grounds for rejection is maintained for reasons of record in Paper No. 11, mailed 12/19/01 and repeated below.**

Each of the claims has the limitation "... transforming a suitable host cell. . . capable of expressing a gene when transformed with an expression vector comprising a nucleic acid encoding . . ." (examiner's emphasis added). The claims are vague and indefinite in that there is no explicit linkage of the nucleic acid to be expressed (i.e. a gene) with the recited gene (e.g. PGU1, etc.). It appears from reading the specification that it is essential to practicing the claimed method that the gene which is expressed be one of the recited genes. It would be remedial to explicitly link the gene which the cell is capable of expressing to the recited gene.

### ***Conclusion***

No claims are allowed.

This is a CPA of applicant's earlier Application No. 09/439,969. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within